UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

GRACEWAY PHARMACEUTICALS, LLC, and 3M INNOVATIVE PROPERTIES CO., **Plaintiffs,** **v.** **PERRIGO COMPANY, PERRIGO ISRAEL PHARMACEUTICALS LTD., and NYCOMED U.S. INC.,** **Defendants.**	**Civil Action Number: 2:10-cv-00937** **OPINION** **HON. WILLIAM J. MARTINI**

MEMORANDUM OPINION

Plaintiffs Graceway Pharmaceuticals, LLC (Graceway) and 3M Innovative Properties Co. (3M IPC) allege that Defendant Nycomed U.S. Inc. (Nycomed) has infringed U.S. Patent No. 7,655,672 (the Patent or the '672 Patent). Defendant Nycomed asserts that the Patent is invalid for indefiniteness and now seeks summary judgment.

For the reasons elaborated below, Defendant Nycomed's motion for summary judgment will be **DENIED.**

I. BACKGROUND AND CONTENTION OF THE PARTIES

This patent action is brought by Plaintiffs Graceway and 3M IPC against Defendant Nycomed[1] for allegedly infringing Graceway's '672 Patent, which was approved on February 2, 2010. Suit was filed February 23, 2010. Doc. No. 214-4. The Patent claims a pharmaceutical cream for topical application composed of imiquimod and oleic acid.

In prior proceedings Graceway moved for a temporary restraining order and preliminary injunction. These motions were denied on March 8, 2010 and on June 10, 2010

[1] Defendants Perrigo Israel Pharms. Ltd. and Perrigo Co. were already terminated from this suit.

respectively. Currently before the Court is Defendant Nycomed's Motion for Summary Judgment for Indefiniteness. Defendant asserts indefiniteness in connection with patent language describing the invention's oleic acid component and in connection with patent language describing imiquimod-related impurities.

The '672 Patent. As explained, the Patent claims a pharmaceutical cream for topical application composed of imiquimod (an immune response modifier) and oleic acid. Claims 1, 7, and 13 recite that the cream is comprised of an "oleic acid component, wherein the oleic acid component at or prior to formulation . . . contains *at least about 80%* oleic acid by weight as a fatty acid." Patent 15, lines 44-48 (emphasis added). *At least about* language relating to the oleic acid component appears in the Patent three times. *Id.*; Patent 16, lines 26-30 (same); Patent 17, lines 12-16 (same).

Also, the claimed formulation is defined in terms of its impurities. Impurity related language appears in the Patent three times. First, claim 1 states:

> [The] pharmaceutical cream contains *imiquimod-related impurities* in an amount of no more than about 0.03% wt./wt. after storage of said pharmaceutical cream at ambient conditions for about 15 days, when absorbance of said pharmaceutical cream is analyzed at about 308 nm using a UV detector.

Patent 15, lines 54-59 (emphasis added).

Second, claim 7 states:

> [The] pharmaceutical cream contains *imiquimod-related impurities* in an amount of no more than about 0.15% wt./wt. after storage of said pharmaceutical cream for *at least about*[2] 2 months at about 40°C. and about 75% humidity, when absorbance of said pharmaceutical cream is analyzed at about 308 nm using a UV detector.

Patent 16, lines 36-43 (emphasis added).

Third, and last, claim 13 states:

> [The] pharmaceutical cream contains *imiquimod-related impurities* in an amount of no more than about 0.29% wt./wt. after storage for *at least about*[3] 4 months at about 40°C. and about 75% humidity, when absorbance of said pharmaceutical cream is analyzed at about 308 nm using a UV detector.

Patent 17, lines 22-27 (emphasis added). The remaining claims, i.e., claims 2-6, 8-12,

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[2] The *at least about* language here does not specifically relate to the oleic acid component.

[3] *Id.*

and 14-20 are dependent on claims 1, 7, and 13.

The parties dispute Defendant Nycomed's contention that both the phrases "at least about 80%" in regard to the oleic acid component and the phrase "imiquimod-related impurities" are indefinite.

II. STANDARD OF REVIEW

Summary Judgment Standard. Summary judgment is appropriate "if the pleadings, the discovery [including depositions, answers to interrogatories, and admissions on file] and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986); *Turner v. Schering-Plough Corp*., 901 F.2d 335, 340 (3d Cir. 1990). A factual dispute is genuine if a reasonable jury could find for the non-moving party, and is material if the factual dispute will affect the outcome of the trial under governing substantive law. *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 248 (1986). At the summary judgment stage, "the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson*, 477 U.S. at 249; *see also Marino v. Indus. Crating Co.*, 358 F.3d 241, 247 (3d Cir. 2004) (holding that a court may not weigh the evidence or make credibility determinations in summary judgment proceedings). Rather, the court must consider all evidence and inferences drawn therefrom in the light most favorable to the non-moving party. *Andreoli v. Gates*, 482 F.3d 641, 647 (3d Cir. 2007).

To prevail on summary judgment, the moving party must affirmatively identify those portions of the record which demonstrate the absence of a genuine issue of material fact. *Celotex*, 477 U.S. at 323-24. The moving party can discharge the burden by showing that "on all the essential elements of its case on which it bears the burden of proof at trial, no reasonable jury could find for the non-moving party." *In re Bressman*, 327 F.3d 229, 238 (3d Cir. 2003); *see also Celotex*, 477 U.S. at 325. If the moving party meets this initial burden, the non-moving party "must do more than simply show that there is some metaphysical doubt as to material facts," but must show sufficient evidence to support a jury verdict in its favor. *Boyle v. County of Allegheny*, 139 F.3d 386, 393 (3d Cir. 1998). However, if the non-moving party "fails to make a showing sufficient to establish the existence of an element essential to [the non-movant's] case, and on which [the non-movant] will bear the burden of proof at trial," Rule 56 mandates the entry of summary judgment because such a failure "necessarily renders all other facts immaterial." *Celotex*, 477 U.S. at 322-23; *Jakimas v. Hoffman-La Roche, Inc*., 485 F.3d 770, 777 (3d Cir. 2007).

If the nonmoving party has the burden of proof at trial, the party moving for summary judgment is not required to "support its motion with affidavits or other similar material negating the opponent's claim," *Celotex*, 477 U.S. at 323, in order to discharge this

"initial responsibility." In this situation, the movant "[merely] show[s]–that is, point[s] out to the district court–that there is an absence of evidence to support the nonmoving party's case." *Id.* at 324.

Legal Standard for Indefiniteness. A statutory presumption of validity applies to any patent approved by the Patent Office. Therefore, the burden of proving a patent's invalidity rests with the party challenging its validity. 35 U.S.C. § 282. In regard to an indefiniteness challenge, 35 U.S.C. § 112(2) provides that "[t]he specification shall conclude with one or more claims particularly pointing out and *distinctly* claiming the subject matter which the applicant regards as his invention." *Id.* (emphasis added). "A determination of claim indefiniteness [under Section 112] is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." *Atmel Corp. v. Info. Storage Devices*, 198 F.3d 1374, 1378 (Fed. Cir. 1999). "In construing claims we search for the ordinary and customary meaning of a claim term to a person of ordinary skill in the art. We determine this meaning by looking first at intrinsic evidence such as surrounding claim language, the specification, the prosecution history, and also at extrinsic evidence, which may include expert testimony and dictionaries." *L.B. Plastics, Inc. v. Amerimax Home Prods., Inc*., 499 F.3d 1303, 1308 (Fed. Cir. 2007). "Absent an express definition in the specification of a particular claim term, the words are given their ordinary and accustomed meaning; if a term of art, it is given the ordinary and accustomed meaning as understood by those of ordinary skill in the art." *Zelinski v. Brunswick Corp*., 185 F.3d 1311, 1315 (Fed. Cir. 1999). "The purpose of expert testimony is to provide assistance to the court in understanding, when the claims are technologically complex or linguistically obscure, how a technician in the field, reading the patent, would understand the claims." *Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.*, 887 F.2d 1070, 1076 (Fed. Cir. 1989) (Newman, J., dissenting).

Specifically, with regard to challenges to a patent based on indefiniteness, the Federal Circuit has held:

> Because the claims perform the fundamental function of delineating the scope of the invention, the purpose of the definiteness requirement is to ensure that the claims delineate the scope of the invention using language that adequately notifies the public of the patentee's right to exclude.
>
> Yet, because claim construction frequently poses difficult questions over which reasonable minds may disagree, proof of indefiniteness must meet an exacting standard. Only claims not amenable to construction or insolubly ambiguous are indefinite. A claim is not indefinite merely because parties disagree concerning its construction. An accused infringer must thus demonstrate by clear and convincing evidence that one of ordinary skill in the relevant art could not discern the boundaries of the claim based on the claim language, the specification, the prosecution history, and the

knowledge in the relevant art.

Haemonetics Corp. v. Baxter Healthcare Corp., 607 F.3d 776, 783 (Fed. Cir. 2010) (citations and quotation marks omitted). If a compound is claimed, it must be identifiable through testing and one skilled in the art must be able to identify if a compound falls within the scope of the claim. *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed. Cir. 1993).

III. ANALYSIS

Defendant Nycomed's motion argues that both the claim terms "imiquimod-related impurities" and "at least about 80%" are indefinite. Plaintiffs take the opposite position.

A. Is *Imiquimod-Related Impurities* Indefinite As A Matter of Law?

Plaintiffs' position is that prior cream formulations using imiquimod and oleic acid resulted in certain less than optimal impurities in the formulation, but that the use of SuperRefined Oleic Acid (SROA) minimized the impurities in the formulation related to imiquimod, that this result was unexpected, and that this result would not have been predicted based on prior art. The key distinction is that Plaintiffs do not claim that the use of SROA minimizes all impurities, but rather, the use of SROA minimizes imiquimod-related impurities, as opposed to those impurities related to the oleic acid component or other components in the formulation described in the Patent.

Claims 1, 7, and 13 use the phrase *imiquimod-related impurities*, and in each case the imiquimod-related impurities are measured at 308 nm. The remaining claims, claims 2-6, 8-12, and 14-20, are dependent on claims 1, 7, and 13. It is these imiquimod-related impurities which define the scope of the Patent. If the phrase has no definite meaning or if there is no way to measure such imiquimod-related impurities, then the "claim is indefinite [because] a skilled artisan cannot determine if an accused product [or formulation] infringes or not . . . ." *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1373 n.12 (Fed. Cir. 2008).

Defendant Nycomed argues that the term is indefinite. *I.e.*, neither the claims, the specification, nor the prosecution supply guidance as to its meaning, nor is it a term of art that would be understood by a person of ordinary skill in the art. Plaintiffs' position, on the other hand, is that a "person having ordinary skill in the art would understand the term 'imiquimod-related impurities' to mean 'impurities resulting from the degradation of imiquimod or from the manufacturing process that show absorbance when analyzed with a UV detector set at *308 nm*.'" Marc B. Brown Decl. ¶ 12, Jan. 27, 2011 (emphasis added), (Doc. No. 220-1). Furthermore, claims 1, 7, and 13 specify that imiquimod-related impurities are measured at 308 nm.

1. *Imiquimod-Related Impurities*, Intrinsic Evidence, and the "Test Method"

The specification describes a "Test Method" used "to determine the amount of impurities in cream formulations containing oleic acid." Patent 13, lines 47-51. The results of the Test Method were incorporated in Table 2.

TABLE 2

	Impurities (%wt/wt)			
Time Point	A	B	C	D
Initial top	0.09	0.08	0.02	0.03
2 months–top	0.25	0.32	0.07	0.09
2 months–bottom	0.33	0.30	0.04	0.15
4 months–top	0.42	0.76	0.18	0.15
4 months–bottom	0.46	0.56	0.04	0.29
6 months–top	0.81	0.30	0.07	0.15
6 months–bottom	0.49	0.29	0.04	0.07[4]

The Test Method does not expressly state that it measures the amount of imiquimod-related impurities. Nor does the remainder of the Patent expressly state that Table 2 measures imiquimod-related impurities. Nycomed points to this lack of clarity as evidence of indefiniteness. *I.e.*, the Patent's claims and specification fail to expressly define *imiquimod-related impurities*.

Turning to the prosecution history, Nycomed points to the Beck and Brown Declarations, which were put before the patent examiner. In support of the application, each of these experts stated:

> Table 1 in the above-identified application . . . describes a series of formulations with either standard or compendia grade oleic acid or Super Refined Oleic Acid NF with or without an antioxidant BHT. Table 2 describes the *imiquimod related impurities* (assayed at 308 nm for this reason) that are observed as a result of these differing compositions. The impurities described in Table 2 refer to *imiquimod degradants* and *related imiquimod substances*, as detected at 308 nm, and not polar impurities associated with oleic acid decomposition.[5]

The two declarations are not as clear as they could be. The shift in language between the second sentence (using *imiquimod-related impurities*) and the third sentence (using

[4] Patent 15, lines 9-26 (citations omitted).

[5] Brown Decl. ¶ 10, Dec. 12, 2008 (emphasis added), (Doc. No. 214-11); Beck Decl. ¶ 10, Dec. 12, 2008 (same), (Doc. No. 214-13).

imiquimod degradants and related imiquimod substances) might indicate that there is some ambiguity. But it appears that the better view is that both experts understood Table 2 to be a measurement of *imiquimod-related impurities* for the formulations described in Table 1. In this sense, the Patent is lexicographically defining the meaning of *imiquimod-related impurities* by Table 2 itself. Furthermore, it is not particularly surprising that Table 2 is merely titled *Impurities*, where, as here, the impurities at issue, those specifically discussed in the claims, are those which are *imiquimod-related*. There is no rule of law requiring each term within a patent to be expressly defined if context, including intrinsic and extrinsic evidence, supplies guidance as to meaning.

2. *Imiquimod-Related Impurities* and Expert Extrinsic Evidence

Nycomed's expert argues that an artisan skilled in the art would find the term *imiquimod-related impurities* indefinite.

Nycomed and its expert, Dr. Schoneich, argue that there are several ways any given "impurity" may be "related" to "imiquimod." An impurity may be (i) a degradation product of imiquimod; (ii) a degradation product of imiquimod degradation products; (iii) compounds that leached from or through the packaging into imiquimod; (iv) compounds left over from the manufacturing process of imiquimod; and/or (v) compounds left from the starting materials used to make imiquimod. The latter two categories include, for example, residual materials, such as solvents and heavy metals, which may be found in commercially sold imiquimod. *See* Schoneich Decl. ¶ 41, Feb. 22, 2011, (Doc. No. 216-6). Defendant does not argue that these impurities are detectable at 308 nm. *Id.* ¶ 46 ("[S]ome compounds that clearly could be 'impurities' that are 'related' to imiquimod, such as heavy metals, residual solvents, oleic acid hydroperoxides or hydroxyl-substituted oleic acid may not necessarily be detected satisfactorily at 308 nm."). Nycomed's position is weak. If these substances are not detectable at 308 nm, then they would appear to be outside of the scope of Table 2 and the Patent's claims. Nycomed argues that this would mean that some imiquimod-related impurities will not be captured by the Test Method, as "not all relevant impurities have substantial absorbance at 308 nm." *Id.* ¶ 60. But this too seems wrong. The Patent's claims expressly adopt the 308 nm test. If this means that some arguably *imiquimod-related impurities* are not captured by the test, then that simply defines the more limited scope of the claims in the Patent. Not only is an inventor entitled to limit the scope of his claims in this manner, his doing so is best practice.

Nycomed notes that in addition to imiquimod, which has its own degradation products, other substances in the claimed formulation, e.g., oleic acid and BHT, also have degradation products. Nycomed's expert argues that some of the degradation products arising from the non-imiquimod substances in the formulation are identical to the degradation products of imiquimod. If that is the case, then some impurities *un*related to

imiquimod may exist in the claimed formulation, and (presumably) these (otherwise identical) non-imiquimod-related impurities will be detected at 308 nm (just as some of the imiquimod degradation products will be). To put it another way, because oleic acid and imiquimod are mixed together in the claimed formulation, it is not possible to determine whether certain degradation products are associated with imiquimod (and, therefore, related to it), or are degradation products associated with the formulation's oleic acid or other components (and, therefore, arguably, not imiquimod-related). *Id.* ¶¶ 54, 58. Schoneich's position is strong, but only as a theoretical matter. He does not actually state that the claimed formulation will actually produce non-imiquimod related impurities which are identical to the imiquimod-related impurities; he only states that the claimed formulation might do so. *Id*. ¶ 56 ("BHT *may* also react with oleic acid-derived hydroperoxides transforming those into a series of products. . . . These products are identical to the product which can form during the oxidation of imiquimod . . . ."). Moreover, Schoneich does not explain whether these products arising from the degradation of substances other than imiquimod will appear in the formulation in any amounts beyond *de minimis* amounts, much less significant amounts (relative to the amounts reported in Table 2). He reports no experiment attempting to measure the size of the effect he describes. *Cf. id.* ¶ 58 (suggesting, unhelpfully, that no such test is possible). Although, Schoneich's evidence is some evidence in support of finding the phrase *imiquimod-related impurities* indefinite, and therefore the Patent invalid, his evidence is neither clear nor convincing.

Schoneich was not the only expert to opine on this question. Again, on behalf of Nycomed, Dr. Potts opined that "[c]ommercially available oleic acid often contains impurities that absorb at 308 nm." Potts Decl. ¶ 12, Feb. 23, 2011 (relying on an article in the *Journal of Lipid Research*), (Doc. No. 214-22). Potts' views, like Schoneich's, are not probative. The journal article Potts cites shows a graph illustrating the absorbance spectra of oleic acid between 200 and 300 nm. This graph does not directly show absorbance at 308 nm. Indeed, in a supplemental filing, Potts reports a magnified view of the graph which might indicate that oleic acid has some absorbance at 308 nm. Supp. Potts Decl. ¶ 4, March 31, 2011, (Doc. No. 228-10).[6] That begs the question why Potts failed to put forward any publication or experiment firmly supporting his view. More importantly, Potts' testimony described testing "commercially available oleic acid" and testing its degradants at 308 nm. However, Potts fails to put forward evidence or support for the position that *in the claimed formulation*, the oleic acid component will react in this manner he describes.

[6] The level of absorbance at 308 nm approaches zero. This does not seem to be the "substantial absorbance" called for by Nycomed's primary expert, Schoneich. *See* Schoneich Decl. ¶ 60.

Finally, Robert J. Nelson, one of the Patent's inventors, stated in a filing submitted to the Patent Examiner, that "[c]ompounds related to oleic acid would *not* show an absorbance at [308 nm]." Decl. ¶ 6, Dec. 12, 2008, (Doc. No. 214-10). Nelson was subsequently pressed on this point. In a deposition in this action, Nelson stated:

> Q. So you don't actually know if those peaks that you counted for [formulations] A, B, C, and D in table 2 were from oleic acids themselves, do you?
>
> A. We believe the absorbance at 308 [nm] would lead us towards imiquimod, but we -- but we don't know.[7]

Nelson stated that he "believed" that testing the formulation at 308 nm would only reveal *imiquimod-related impurities*, but he admits that he is not sure. He admits the possibility that a 308 nm test might reveal some substance that is not imiquimod-related. *See also* Marc. B. Brown Decl. 295:14-23, March 1, 2011 (same), (Doc. No. 227-3). Brown and Nelson's evidence admit a possibility, but that is all. It seems that in order to render the Patent's term indefinite, there must be evidence of more than a possibility. There should be direct testimony (based on treatises or other support) or experimental evidence establishing that in the context of the claimed formulation, the 308 nm Test Method would reveal substances that are not *imiquimod-related*. Anything less would not appear to meet the clear and convincing evidence standard.

B. Is *At Least About 80%* Indefinite?

Defendant Nycomed's position is that a person of ordinary skill in the art would not know if the lower bound of *at least about 80%* is 79.5%, 79%, 75% or some other amount altogether. Plaintiff Graceway takes the position that *at least about 80%* would have been understood by one of ordinary skill in the art to have permitted "up to a 10% deviation" from the claimed amount of 80%, therefore, *at least about 80% oleic acid* means "at least 72% oleic acid."

Federal appellate authority has at times approved and at times rejected the use of *at least about*-type-language in a patent. *Compare Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1367-71 (Fed. Cir. 2008) (approving use of "greater than about" language in a patent), *with Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1218 (Fed. Cir. 1991) (affirmed the district court's holding that the phrase "at least about 160,000 IU per absorbance unit" in a patent was indefinite).[8] District court authority is likewise divided.[9]

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[7] Robert J. Nelson Dep. 84:16-22, Oct. 29, 2010, (Doc. No. 216-1).

[8] The Federal Circuit's *Amgen* holding – finding "at least about" indefinite – applies "especially when there is close prior art." *Amgen*, 492 F.3d at 1347. Here, Plaintiffs' Patent did not distinguish what was claimed from prior art. Therefore, *Amgen* is not on-

As a result there is no bright line rule. Rather, whether such language in a patent will withstand an indefiniteness attack will depend on the facts and circumstances of each case, and, in particular, whether the patent, other intrinsic evidence, or the extrinsic evidence supplies guidance such that a person of ordinary skill in the art could determine the metes and bounds of the invention claimed. *See Amgen*, 927 F.2d at 1218; *Young v. Lumenis, Inc*., 492 F.3d 1336, 1346-47 (Fed. Cir. 2007).

At this juncture, the question is not whether the Court can construe the term. No *Markman*[10] hearing has taken place. At this stage, the question is purely one of summary judgment: whether or not the evidence submitted by the parties in support of and in opposition to the motion establishes a genuine issue of material fact. Fed. R. Civ. P. 56. Here, Nycomed's prior filings with the Court,[11] and the materials Nycomed exchanged with Plaintiffs in contemplation of *Markman* proceedings[12] indicate that Nycomed could determine the meaning of "at least about 80%."

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point.

[9] The federal district courts are likewise divided. *Compare, e.g., Kimberly-Clark Worldwide, Inc. v. First Quality Baby Prods., LLC*, 2011 WL 871479, at *4 (M.D. Pa. March 1, 2011) ("However, this case concerns claim terms with additional modifying language of 'at least.' There is simply no intrinsic evidence that the word 'about' coupled with 'at least' has an accepted meaning."), *and Hamilton Prods., Inc. v. O'Neill*, 492 F. Supp. 2d 1328, 1336-41 (M.D. Fla. 2007) (holding that "less than approximately 0.8 [inches]" was indefinite), *with ReedHycalog UK, Ltd. v. United Diamond Drilling Servs., Inc*., 2009 WL 1011730, at *4 (E.D. Tex. April 15, 2009) (affirming in *ipse dixit* that "the term 'at least about 0.1 mm' is not limited to 'a minimum of 0.1 mm.' The terms 'at least about 0.1 mm' and 'at least 0.1 mm' are easily understood terms and do not require construction.").

[10] *Markman v. Westview Instruments, Inc*., 52 F.3d 967 (Fed. Cir. 1995) (en banc).

[11] *See, e.g.*, Broom Decl. ¶ 22, April 16, 2010 ("Nycomed can use oleic acid in its product that has less than the 'at least about 80%' oleic acid and Nycomed intends to use this oleic acid in the product it makes, uses and sells in the future."). A fair implication of the Declaration is that Nycomed could construe the disputed claim term: "at least about 80%." Nycomed submitted this document to the Court during the prior temporary restraining order proceedings.

[12] *See, e.g*., Nycomed's Revised Non-Infringement Contention Disclosure, at 10 (Oct. 8, 2010); *id*. at 31 ("Since there is no guidance in the specification as to what 'about' means, a [person of ordinary skill in the art] would limit 'about' to mean at most up to the next available integer, which is 79%."); *id*. Ex. at 20; *see also, e.g*., Defendant Nycomed US Inc.'s Preliminary Claim Construction *passim* (Oct. 2010).

Additionally, Plaintiffs' opposition brief is supported with expert testimony. Keith A. Johnson Decl. ¶ 17, Mar. 18, 2011, (Doc. No. 220-11). In his deposition, Johnson relied on two treatises. *See Guidance for Industry Nonsterile Semisolid Dosage Forms: Scale-up and Post-Approval Changes* (May 1997) and *European Pharmacopoeia*. Although Nycomed's experts' evidence contradicts the evidence put forward by Johnson, the Court cannot wholly discount Johnson's evidence, nor does summary judgment allow the Court to weigh the evidence put forth by the rival experts.

Johnson's testimony is some evidence that the term "at least about 80%" is not indefinite. Nycomed's prior filings (with the Court and with Plaintiffs) is other such evidence. For all these reasons, the Court cannot conclude, at this juncture, that Nycomed has met its burden to establish that there is no material fact in dispute.

IV. CONCLUSIONS

For the reasons elaborated above, Defendant Nycomed's motion for summary judgment is **DENIED.**

s/ William J. Martini

DATE: July 27, 2011 **William J. Martini, U.S.D.J.**